JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

JAMES KRAMMES AND DEBORAH KRAMMES

(b) County of Residence of First Listed Plaintiff Schuylkill
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)
James R. Ronca, Esquire ANAPOL SCHWARTZ
1710 Spruce St. Philadelphia, PA 17103 (215) 735-1130

DEFENDANTS

Zimmer, Inc. and Zimmer Holdings

County of Residence of First Listed Defendant Kosciusko
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal Question (U.S. Government Not a Party)
- ❒ 2 U.S. Government Defendant
- ☒ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	☒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

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- ❒ 950 Constitutionality of State Statutes

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from another district (specify) ❒ 6 Multidistrict Litigation ❒ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing **(Do not cite jurisdictional statutes unless diversity)**:
28 U.S.C. §1332

Brief description of cause:
Personal Injury-negligence, strict liability, failure to warn, defective design, breach of express warranty, etc.

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☑ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
05/13/2011

SIGNATURE OF ATTORNEY OF RECORD
/s/ James R. Ronca

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF PENNSYLVANIA

JAMES KRAMMES and DEBORAH KRAMMES h/w Plaintiffs, v. ZIMMER, INC.; & ZIMMER HOLDINGS, INC. Defendants.	Court File No. **COMPLAINT - JURY TRIAL DEMAND**

COMES NOW the Plaintiffs, James Krammes and Deborah Krammes h/w, by and through their undersigned Counsel, and for their Complaint against the Defendants, allege as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by James Krammes, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement products, the Zimmer NexGen Legacy Posterior Stabilized High Flex ("LPS High Flex") femoral component and the NexGen MIS Stemmed Tibial component ("MIS Tibial") of the Zimmer NexGen total knee replacement system.

2. The Zimmer LPS High Flex femoral component was developed, designed, manufactured, distributed, sold and deliberately promoted by Defendants as an improvement and additional option to the Zimmer NexGen Legacy Posterior Stabilized

("LPS"), another femoral component developed, designed, manufactured, distributed and sold by Defendants. Defendants specifically promoted the LPS High Flex as accommodating "a higher range of motion" and helping patients "maintain an active lifestyle after a total knee replacement."

3. In a total knee arthroplasty, the femoral component options, such as the LPS High Flex or the LPS, are used in conjunction with a patellar component and a tibial component option, such as the MIS Tibial, together, to form the Zimmer NexGen Complete Knee Solution system (all components collectively hereinafter "Zimmer NexGen Knee").

4. Defendants knew or should have known that the LPS High Flex and MIS Tibial, when used within the Zimmer NexGen Knee, can loosen in patients, such as Plaintiff James Krammes, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery and/or knee replacement.

5. The LPS High Flex was defectively designed, developed, manufactured and sold because its increased failure rate and risk of revision is unreasonably greater than other knee implants such as the LPS which achieve the same degree of mobility. The LPS High Flex has no clinical benefit over the LPS that compensates in whole or part for the increased risk. Further, Defendants misled health care professionals and the public into believing that the use of the LPS High Flex in the Zimmer NexGen Knee was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to

utilize the LPS High Flex, even though Defendants knew or should have known that the LPS High Flex was unreasonably unsafe; and failed to warn health care professionals and the public of the increased risk of failure associated with the LPS High Flex while offering little to no additional benefit over the Zimmer LPS.

6. The MIS Tibial was defectively designed, developed, manufactured and sold because the increased failure rate and risk of revision is unreasonably greater than other standard tibial components. The MIS Tibial has no clinical benefit over the standard tibial component that compensates in whole or part for the increased risk. Further, Defendants misled health care professionals and the public into believing that the use of the MIS Tibial in the Zimmer NexGen Knee was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince health care professionals to utilize the MIS Tibial, even though Defendants knew or should have known that the MIS Tibial was unreasonably unsafe; and failed to warn health care professionals and the public of the increased risk of failure associated with the MIS Tibial while the benefits do not outweigh the risks .

PARTIES

7. Plaintiffs James Krammes and Deborah Krammes are citizens of the Commonwealth of Pennsylvania, and reside in Pottsville, Pennsylvania.

8. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

9. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

10. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen Knee, the LPS High Flex and MIS Tibial. Defendants' products, including the Zimmer NexGen Knee, LPS High Flex and MIS Tibial are sold throughout the world, including within the Commonwealth of Pennsylvania.

JURISDICTION AND VENUE

11. Jurisdiction over this action exists under 28 U.S.C. §1332, based on diversity of citizenship and an amount in controversy that exceeds $75,000 exclusive of interest and costs.

12. Venue is proper in this district pursuant to 28 U.S.C. §1961, *et seq*., because a substantial part of the events giving rise to this claim occurred in Pennsylvania and this district.

FACTUAL BACKGROUND
KNEE REPLACEMENT BACKGROUND

13. Total knee arthroplasty (TKA), also called total knee replacement, is a commonly performed medical procedure. The surgery is designed to help relieve pain and improve joint function, generally in people with severe knee degeneration due to arthritis or trauma.

14. The TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed or reduced as is often the underside of the kneecap (patella).

15. About 85 to 90 percent of total knee replacements are successful up to ten years.

16. Mechanical loosening means that the attachment between the artificial knee and the bone has become loose.

17. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

18. Loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. Images of a loose knee joint are one or more radiolucent lines around the contours of the artificial knee joint.

19. A loose artificial knee causes pain and wearing away of the bone. A loose artificial knee can involve a severe psychical burden for the patient and severely restrict the patient's daily activities.

20. Once the individual loses function of the knee or the pain becomes unbearable, another operation can be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

21. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

22. Upon information and belief, in an operation revising a total knee failure due to loosening, the most significant problem is the reconstruction of the severe bone loss caused by the failed total knee prosthesis. The bone loss makes it difficult to restore the stability in the revised total knee.

23. Upon information and belief, the success rate of a revision operation is lower than the initial total knee replacement and the risks and complications are higher. The range of motion in the knee after revision surgery may decrease and the walking capacity may be also diminished. The rate of an artificial knee replacement loosening is higher after revision surgery than in primary knee replacement surgery.

ZIMMER NEXGEN KNEE FACTS

24. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

25. In 1995 Zimmer received 510(k) approval from the U.S. Food and Drug Administration ("FDA") for its NexGen Complete Knee Solution system.

26. Thereafter, in 1999 Zimmer received FDA 510(k) approval of its first LPS high flex femoral component design for its Zimmer NexGen Knee line, whereby the maximum active flexion angle was increased from 120 degrees to 155 degrees.

27. The Zimmer NexGen Knee uses a "high-flex" femoral component that purports to allow a greater degree of flexion than the standard femoral component.

28. Zimmer High Flex femoral components are marketed as specifically designed for total knee replacement patients "expecting to maintain an active lifestyle".

To achieve these goals, the design of the LPS High-Flex femoral components allows for knee flexion up to 155 degrees compared to the standard knee replacement which only allows for flexion up to 120 degrees.

29. The Zimmer NexGen Knee also uses a stemmed tibial component that is designed to be assembled within the patient thereby allowing for minimally invasive surgery techniques.

30. In March 2005 Zimmer received 510(k) FDA approval for the NexGen MIS Tibial components that are part of the NexGen system of semiconstrained, nonlinked, condylar knee prostheses.

31. The low profile design of this tibial component was developed and manufactured by Zimmer to allow for implantation and assembly in minimally invasive knee replacement surgeries. Wherein a standard knee replacement surgery the incision is about eight inches, a minimally invasive surgery only requires a four to five inch incision.

32. Indeed, a strong emphasis of Zimmer's marketing of the Zimmer NexGen Knee was the allure of the "minimally invasive" surgery, so much so that Zimmer went to the extensive effort to trademark the term "MIS" or "Minimally Invasive Solutions."

33. Zimmer MIS Tibial components were marketed as "specifically designed to address the challenges and demands of minimally invasive TKA." To achieve these goals, the design incorporated broad proximal fins that engage the tibia, while its low profile makes it easier to insert.

34. Zimmer went on to boast through promotional materials intended to induce physicians and patients in the use of the MIS Tibial that "MIS procedures are less invasive with smaller incisions, reduced blood loss, less pain and shorter hospital stays."

35. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of a medical device, and by said activities, caused the Zimmer NexGen Knee, the LPS High Flex, and MIS Tibial to be placed into the stream of commerce throughout the United States.

36. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen Knee, the LPS High Flex, and MIS Tibial.

37. Upon information and belief, Defendants were in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen Knee, the LPS High Flex and MIS Tibial.

38. Defendants were at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen Knee, the LPS High Flex, and MIS Tibial.

39. At various times material and relevant hereto in the last two decades, Defendants jointly or individually sought approval from the FDA for the sale and marketing of the Zimmer NexGen Knee, the LPS High Flex, and MIS Tibial.

40. In seeking approval for the sale of the LPS High Flex and MIS Tibial, Defendants represented that each of the devices was substantially equivalent to a previously approved or predicate device and therefore could receive premarket approval under Section 510(k) of the FDA.

41. By claiming substantial equivalence, Defendants knew the LPS High Flex and MIS Tibial were subject to less testing and scrutiny.

42. The LPS High Flex, MIS Tibial and the Zimmer NexGen Knee have been widely advertised, marketed and represented by the Defendants as safe and effective total knee prosthesis.

43. The LPS High Flex and MIS Tibial were aggressively marketed and promoted to the more active population, including Plaintiff, requiring knee replacement surgery as the state-of-art knee replacement implant providing greater flexion up to 155 degrees, and allowing for minimally invasive knee replacement.

ZIMMER NEXGEN KNEE PROBLEMS

44. A 2005 study published in the Journal of Bone and Joint Surgery by Young-Hoo Kim titled, *Range of Motion of Standard and High-Flexion Posterior Stabilized Total Knee Prostheses*, showed no statistical significance between the degree of flexion in the group with the LPS and the group with the LPS-Flex. After two years

the mean range of motion in the LPS group was 136 degrees and the LPS-Flex group was 139 degrees.

45. In 2007, The Journal of Bone and Joint Surgery (British Edition), published a peer reviewed study by professors at the Seoul National University College of Medicine titled, *High Incidence of Loosening of the Femoral Component in the Legacy Posterior Stabilised-Flex Total Knee Replacement*. The study showed that 38% of the implanted LPS high flex knees were loose shortly after 2 years post implant. From the group of patients with loose knees, over half (56%) had their knee revised due to pain.

46. In March 2010, Dr. Steven Weeden, of the Texas Hip and Knee Center, presented at a national meeting of the American Association of Orthopedic Surgeons a study reporting a higher than expected rate of early loosening in cemented primary total knee replacements when a MIS Tibial component was used without an additional modular stem. In the MIS tibias components placed without an additional modular stem the failure rate was 24% versus 4.2% with a stem.

47. On or around April 2010, Defendants sent an "Urgent Field Safety Notice"/"Urgent Device Correction" letter to all customers using the MIS Tibial.

48. In that letter, Defendants acknowledged, in a stunning reversal of prior promotion and marketing of the MIS Tibial, that the prior procedures were wrong and potentially dangerous.

49. Specifically, whereas before Defendants marketed MIS procedures, including the MIS Tibial as "less invasive with smaller incisions, reduced blood loss, less pain and shorter hospital stays," ***now*** Defendants admitted that "MIS procedures are

inherently challenging and can involve reduced visibility, which may lead to difficulty with achieving proper implant alignment and cement fixation."

50. Defendants went on to alert physicians that "Required Actions" included "destroy or disregard all previous versions of the surgical technique [MIS]."

51. Finally, Defendants advised customers of a change in labeling and recommended usage of the MIS Tibial:

> Zimmer is enhancing the labeling for the NexGen MIS Tibial Component in several important ways. The changes to the labeling include the following recommendations:
>
> 1. to achieve adequate visualization and access if an MIS approach is used,
>
> 2. to use a drop down stem extension with the NexGen MIS Tibial Component,
>
> 3. to fully cement and pressurize the anterior and posterior surfaces of the tibial component, and
>
> 4. to carefully use bone cement application per the manufacturer's instructions.

52. On September 13, 2010, the FDA classified the Defendants efforts relating to the MIS Tibial components as a Class II Recall.

53. From the time that Defendants first began selling the Zimmer NexGen Knee in the United States, the product labeling and product information for the Zimmer NexGen Knee failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen Knee can loosen in patients.

54. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen Knee, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen Knee was safe.

55. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen Knee and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen Knee by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

PLAINTIFF FACTUAL ALLEGATIONS

56. On August 1, 2008, Plaintiff's physician implanted a Zimmer NexGen Knee system including a NexGen LPS High Flex femoral component and a MIS Tibial.

57. Prior to August 1, 2008, the treating physician for Plaintiff, as well as Plaintiff, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

58. Plaintiff James Krammes and Plaintiff's physician, either through direct promotional contact with Sales Representative Defendants, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Zimmer NexGen Knee was safe and effective for use in TKA procedures.

59. Plaintiff returned to Plaintiff's physician several times due to consistent pain relating to his Zimmer NexGen Knee.

60. On or about August 24, 2009 x-rays revealed for the first time prosthetic loosening.

61. On September 30, 2009, Plaintiff had a second surgery to revise/replace his MIS Tibial and LPS High Flex due to loosening. At the time of the surgery Plaintiff's doctor discovered a lack of boney ingrowth with the femoral component, delamination of the tibia component and loosenening of the posterior pegs. The implant was revised with Zimmer NexGen LPS femur, extra stemmed length tibial component and a LCCK spacer.

62. On June 23, 2010, Plaintiff had a third surgery to revise/replace his implant due to possible nickel allergy.

63. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

64. As a direct and proximate result of the use of the Zimmer NexGen Knee, Plaintiff incurred, and continues to incur, medical expenses to treat his injuries and condition.

65. At no time material to his use of the Zimmer NexGen Knee was Plaintiff or his physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen Knee.

COUNT I - STRICT LIABILITY
PLAINTIFFS V. DEFENDANTS

66. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

67. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen Knee, the LPS High Flex and MIS Tibial. Defendants designed, manufactured, marketed, and sold Zimmer NexGen Knee, the LPS High Flex and MIS Tibial to medical professionals and their patients, knowing they would be implanted for knee replacements.

68. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial were designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and were used by Plaintiff in a reasonably foreseeable and intended manner.

69. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial were "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen Knee, the LPS High Flex and MIS Tibial were in a condition not suitable for their proper and intended use among patients.

70. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial were used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

71. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the Zimmer NexGen Knee, the LPS

High Flex and MIS Tibial. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer NexGen Knee, the LPS High Flex and MIS Tibial in such a way as to increase the risk of harm or injury to the recipients of them.

72. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial are defective in design because of their propensity to loosen and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

73. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial are defective in design because the increased risk for failure requiring revision surgery is unreasonably greater than other knee implants such as the LPS. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial offers no clinical benefit over the LPS or the standard tibial that compensates in whole or part for the increased risk.

74. The Zimmer NexGen Knee, the LPS High Flex and MIS Tibial are unreasonably dangerous because they were sold to Plaintiff without adequate warnings regarding, *inter alia,* the propensity of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen Knee, LPS High Flex, and MIS Tibial; and the probability of suffering loosening and revision surgery.

75. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and

marketable at the time Defendants sold Zimmer NexGen Knee, the LPS High Flex, and MIS Tibial to Plaintiff.

76. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial are unreasonably dangerous because they were sold to Plaintiff without adequate warnings regarding, *inter alia,* the increased risk of failure of Zimmer NexGen Knee, LPS High Flex, and MIS Tibial resulting in revision surgery which is unreasonably greater than other knee implants such as the LPS and standard tibial. The LPS High Flex and MIS Tibial offer no clinical benefits over the LPS and standard tibial that compensates in whole or part for the increased risk.

77. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and his physicians that Zimmer NexGen Knee, LPS High Flex and MIS Tibial cause serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

78. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer NexGen Knee, the LPS High Flex and MIS Tibial, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is

entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

79. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II - NEGLIGENT FAILURE TO WARN
PLAINTIFFS V. DEFENDANTS

80. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

81. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

82. Defendants failed to adequately warn health care professionals and the public, including Plaintiff James Krammes and his prescribing physician, of the true risks of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, including that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

83. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

84. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, without causing serious pain and injury to patients, including Plaintiff.

85. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction

because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer NexGen Knee, LPS High Flex, MIS Tibial and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

86. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial, which were researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the LPS High Flex and MIS Tibial resulting in revision surgery while knowing that a safer alternative design, the LPS and standard tibial existed. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the LPS High Flex and MIS Tibial, even though it provides no clinical benefits over other knee replacement systems such as the LPS and standard tibial and had a higher failure rate than the LPS and standard tibial.

87. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

88. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

89. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III – NEGLIGENT DESIGN DEFECT
PLAINTIFFS V. DEFENDANTS

90. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

91. Defendants is the researcher, developer, designer, manufacturer, distributor, marketer, promoter, supplier and seller of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, which is defective an unreasonably dangerous to consumers.

92. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial are defective in their design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial are defective in design or formulation in that they lack efficacy and/or they pose a greater likelihood of

injury than other knee replacement devices and similar knee replacement devices on the market and are more dangerous than ordinary consumers can reasonably foresee.

93. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial did not outweigh the risk of marketing a product designed in that manner.

94. The defective condition of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial rendered it unreasonably dangerous and/or unreasonably safe, and the Zimmer NexGen Knee, LPS High Flex and MIS Tibial were in this defective condition at the time it left the hands of the Defendants. The Zimmer NexGen Knee, LPS High Flex, and MIS Tibial was expected to and did reach consumers, including Plaintiff James Krammes, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

95. Plaintiff and his physician were unaware of the significant hazards and defects in the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

96. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, it was being utilized in a manner that was intended by Defendants.

97. At the time Plaintiff received and used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, it was represented to be safe and free from latent defects.

98. Defendants were negligent for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

99. Defendants knew or should have known of the dangers associated with the use of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, as well as the defective nature of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, but continued to design, manufacture, sell, distribute, market, promote and/or supply the Zimmer NexGen Knee, LPS High Flex and MIS Tibial so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

100. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries.

101. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV – NEGLIGENCE
PLAINTIFFS V. DEFENDANTS

102. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

103. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, including a duty to ensure that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial did not pose a significantly increased risk of bodily injury to its users.

104. Defendants had a duty to exercise reasonable care in the advertising and sale of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, including a duty to warn Plaintiff and other consumers, of the dangers associated with the Zimmer NexGen Knee, LPS High Flex, and MIS Tibial that were known or should have been known to Defendants at the time of the sale of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial to the Plaintiff.

105. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial because Defendants knew or should have known that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial had a propensity to cause serious injury,

including loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

106. Defendants failed to exercise ordinary care in the labeling of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the risk of serious injury, including, loosening and revision surgery.

107. Defendants failed to exercise ordinary care in the labeling of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial and failed to issue adequate pre-marketing or post-marketing warnings to doctors and the general public, including Plaintiff, regarding the increased risk of failure when compared to the comparable LPS and standard tibial while the LPS High Flex and MIS Tibial offer no clinical benefits over the LPS and standard tibial that compensates in whole or part for the increased risk.

108. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

109. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

110. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, labeling, warnings and distribution of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, Plaintiff was implanted with the Zimmer NexGen Knee, LPS High Flex and MIS Tibial and suffered severe and debilitating injuries, economic loss,

and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

111. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V - BREACH OF EXPRESS WARRANTY
PLAINTIFFS V. DEFENDANTS

112. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

113. Defendants advertised, labeled, marketed and promoted its product, the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, representing the quality to health care professionals, the FDA, Plaintiff James Krammes, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial would conform to the representations. More

specifically, Defendants represented that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial were safe and effective, that they were safe and effective for use by individuals such as Plaintiff, that they were safe and effective to treat Plaintiff's condition, that it provided an improved implant fit, increased flexion, fewer intraoperative adjustments, less soft-tissue irritation and/or was specifically designed to alleviate knee pain, restore mobility, offer optimal fit and functionality, smaller incision/scar, and shorter recover time.

114. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

115. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial did not conform to the representations made by Defendants in that the Zimmer NexGen Knee, LPS High Flex, and MIS Tibial was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, was not safe and effective to treat Plaintiff's condition, did not provide an improved implant fit, did not result in fewer intraoperative adjustments, caused soft-tissue irritation and/or did not alleviate knee pain, restore mobility, or offer optimal fit and functionality.

116. At all relevant times, Plaintiff used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial for the purpose and in the manner intended by Defendants.

117. Plaintiff and Plaintiff's physician, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

118. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

119. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, Plaintiff was implanted with the Zimmer NexGen Knee, LPS High Flex, and MIS Tibial and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

120. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI - BREACH OF IMPLIED WARRANTY
PLAINTIFFS V. DEFENDANTS

121. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

122. The Zimmer NexGen Knee, LPS High Flex and MIS Tibial was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor were the Zimmer NexGen Knee, LPS High Flex and MIS Tibial minimally safe for the expected purpose.

123. At all relevant times, Plaintiff used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial for the purpose and in the manner intended by Defendants.

124. Plaintiff and Plaintiff's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

125. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

126. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, Plaintiff was implanted with the Zimmer NexGen Knee, LPS High Flex and MIS Tibial and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

127. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII - NEGLIGENT MISREPRESENTATION
PLAINTIFFS V. DEFENDANTS

128. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

129. Prior to the Plaintiff receiving the Zimmer NexGen Knee, LPS High Flex and MIS Tibial Defendants misrepresented that the Zimmer NexGen Knee, LPS High Flex and MIS Tibial were a safe and effective total knee replacement system.

130. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial, including information regarding increased risk of failure, harmful side-effects, increased risk of revision surgery and results of peer reviewed studies showing an increased risk of revision with little to no clinical benefit over the comparable LPS and standard tibial knee implant.

131. Defendants had a duty to provide Plaintiffs, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

132. Defendants knew or should have known; based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer NexGen Knee, LPS High Flex and MIS Tibial that their representations regarding the Zimmer NexGen Knee, LPS High Flex and MIS Tibial were false, and that they had a duty to disclose the dangers associated with the device.

133. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

134. Plaintiff and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

135. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial was the direct and proximate cause of Plaintiff's injuries.

136. Defendants' conduct, as described above, was extreme and outrageous. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn

or inform the unsuspecting consuming public. Defendants' outrageous conduct warrants an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII - VIOLATION OF CONSUMER PROTECTION LAWS
PLAINTIFFS V. DEFENDANTS

137. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows.

138. Plaintiff purchased and used the Zimmer NexGen Knee, LPS High Flex and MIS Tibial primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

139. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. Representing that goods or services have characteristics, ingredients, uses, benefits or qualities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

140. Defendants violated consumer protection laws through their use of false and misleading misrepresentations or omissions of material fact relating to the safety and effectiveness of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

141. Defendants uniformly communicated the purported benefits of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial while failing to disclose the serious and dangerous side-effects related to the Zimmer NexGen Knee, LPS High Flex and MIS Tibial and of the true state of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial the, regulatory status, its safety, its efficacy, and its true usefulness. Defendants made these representations to physicians, the medical community at large, and to patients and consumers such as Plaintiff in their marketing and advertising.

142. Defendants conduct in connection with the Zimmer NexGen Knee, LPS High Flex and MIS Tibial the was also impermissible and illegal in that it created a likelihood of confusion and misunderstanding, because Defendants misleadingly, falsely, and or deceptively misrepresented and omitted numerous material facts regarding, among other things, the utility, benefits, costs, safety, efficacy, and advantages of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial.

143. As a result of these violations of the consumer protection laws, Plaintiff has incurred and will incur, serious physical injury, pain, suffering, loss of income, loss of opportunity, loss of family and social relationships and medical, hospital and surgical expenses and other expense related to the failure of the Zimmer NexGen Knee, LPS High Flex and MIS Tibial the implant Plaintiff received and the resulting revision surgery.

WHEREFORE**,** Plaintiffs demand judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX - LOSS OF CONSORTIUM
PLAINTIFF, DEBORAH KRAMMES V. DEFENDANTS

144. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

145. Plaintiff, Deborah Krammes, was at all times relevant hereto the spouse of plaintiff, James Krammes, and as such lives and cohabits with him.

146. For the reasons set forth herein, Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, and for medications, and will necessarily incur further expenses of a similar nature in the future.

147. For the reasons set forth herein, Plaintiff has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society and the ability of the Plaintiff's spouse have in those respects been impaired and depreciated, and the martial association between husband and wife has been altered, and accordingly, the Plaintiff has been caused great mental anguish.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

1. Compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

2. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

3. Double or triple damages as allowed by law;

4. Attorneys' fees, expenses, and costs of this action;

5. Punitive damages, in an amount to be determined at trial;

6. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and

7. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: May 13, 2011

Anapol Schwartz Weiss Cohan
Feldman & Smalley, P.C.

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